

REMARKS

The November 2, 2006 Official Action and the references cited therein have been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set forth in the November 2, 2006 Official Action. Therefore, the initial due date for response is February 9, 2007.

The Examiner has rejected claims 1-5, 25-28, and 33 for allegedly failing to satisfy the written description requirement of 35 U.S.C. §112, first paragraph.

The Examiner has rejected claim 2 under 35 U.S.C. §102(b) as allegedly anticipated by GenBank Accession No. Y12377. Claims 2 and 33 have also been rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent 5,474,796.

The foregoing rejections constitute all of the grounds set forth in the November 9, 2006 Official Action for refusing the present application.

In accordance with the instant amendment, Applicant has amended claims 2 and 33. Support for the amendment to claim 2 is inherent in the claim as previously presented. Support for the amendment to claim 33 can be found, for example, at page 18, lines 26-33.

No new matter has been introduced into this application by reason of any of the amendments presented herewith.

In view of the present amendment, Applicant respectfully submits that the 35 U.S.C. §112, first paragraph rejection of claims 1-5, 25-28, and 33 and the 35 U.S.C. §102(b) rejections of claims 2 and 33, as set forth in the November 9, 2006 Official Action, cannot be maintained.

CLAIMS 1-5, 25-28, AND 33 SATISFY THE REQUIREMENTS OF 35

U.S.C. §112, FIRST PARAGRAPH

The Examiner has rejected claims 1-5, 25-28, and 33 for allegedly failing to satisfy the written description requirement of 35 U.S.C. §112, first paragraph. It is the Examiner's position that the claims encompass a large genus of sequences and that the specification does not "teach the percent structural identity needed for a sequence to be considered FGF3." Applicant continues to respectfully disagree with the Examiner's position for the reasons of record and those set forth below.

At the outset, the Examiner asserts at page 8 of the instant Official Action that "the specification only describes SEQ ID NO: 1 in terms of the FGF3 gene." This is wholly incorrect. The instant specification discloses that SEQ ID NO: 1 was operably linked with to the firefly luciferase gene (see page 23). The results presented in Table 1 (page 24) clearly demonstrate that SEQ ID NO: 1 affected the transcription of the luciferase gene. Furthermore, SEQ ID NO: 1 was cloned into plasmid pGL3 with the firefly luciferase gene. Accordingly, the sequences flanking SEQ ID NO: 1 on both the 5' end and the 3' end were completely different than the sequences which flank SEQ ID NO: 1 in the context of the FGF3 gene. Obviously, the sequences which flank SEQ ID NO: 1 can be any sequence.

Claim 1 encompasses sequences which comprise SEQ ID NO: 1. SEQ ID NO: 1 is provided in the instant specification and it is clear that the sequences which flank SEQ ID NO: 1 can be any sequence. Nothing more is needed to satisfy the written description requirement. Indeed, it is standard practice for the USPTO to determine that claims drawn to isolated nucleic acids comprising novel genes satisfy the written description requirement. No more is necessary for the instant application.

The Examiner also states at page 8 of the instant Official Action that the "claims encompass mutants, variants,

and homologs from any source not just the FGF3 gene." As stated at pages 12 and 13 of the instant specification, the nucleic acid molecules comprising SEQ ID NO: 1 can be, for example, synthesized *in vitro* or isolated from biological sources. The source of the sequence is immaterial. SEQ ID NO: 1 is provided and that is all that is needed to satisfy the written description requirement. It appears that the Examiner may be arguing the existence of the sequence in other sources, but as evidenced by the lack of a rejection of claim 1 under 35 U.S.C. §102, such an argument cannot be reasonably maintained.

With regard to claim 2, Applicant has amended the claim to recite "a sequence which is the **complete** complement of the sequence of claim 1." Inasmuch as SEQ ID NO: 1 is provided and fully described in the instant specification, it is clear that the complete complement is fully described.

As to claims 25-28 and 33, Applicant respectfully submits that claims 25-28 are drawn to kits which comprise a) a first oligonucleotide probe selected from the group consisting of SEQ ID NOS: 6 and 7 and b) a pair of primers wherein the primers are selected from the group consisting of SEQ ID NOS: 4 and 5. Additionally, claim 33, as amended, recites a microarray "wherein at least one of the oligonucleotide probes is selected from the group consisting of SEQ ID NOS: 6 and 7." Inasmuch as each of SEQ ID NOS: 4-7 is provided in the instant specification, it is evident that claims 25-28 and 33 are fully described in the instant application.

In light of the foregoing, Applicant respectfully submit that the written description rejection of claims 1-5, 25-28 and 33 cannot be reasonably maintained. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

**CLAIMS 2 AND 33, AS AMENDED, ARE NOT ANTICIPATED BY THE
REFERENCES CITED BY THE EXAMINER**

The Examiner has rejected claim 2 under 35 U.S.C. §102(b) as allegedly anticipated by GenBank Accession No. Y12377 and claims 2 and 33 under 35 U.S.C. §102(b) as allegedly anticipated the '796 patent. The Examiner contends that while GenBank Accession No. Y12377 is not the complement of SEQ ID NO: 1, fragments of GenBank Accession No. Y12377 are 100% identical to SEQ ID NO: 1 and are, therefore, "fully complementary," as recited in previously presented claim 1. It is also the Examiner's position that certain of the 10-mer oligonucleotides disclosed by the '796 patent are "fully complementary" to SEQ ID NO: 1 and that the microarrays disclosed by the '796 patent satisfy the features recited in claim 33.

As stated hereinabove, Applicant has amended claim 2 to recite "a sequence which is the complete complement of the sequence of claim 1." Inasmuch as GenBank Accession No. Y12377 and the '796 patent fail to disclose a sequence which is complete complement of SEQ ID NO: 1, the instant rejection has been overcome.

With regard to claim 33, Applicant has amended the claim to recite a microarray "wherein at least one of the oligonucleotide probes is selected from the group consisting of SEQ ID NOS: 6 and 7." The '796 patent discloses an array with every possible permutation of the 10-mer oligonucleotide. However, SEQ ID NOS: 6 and 7 are 22 oligonucleotides in length. Accordingly, the '796 fails to teach each and every element of the instantly claimed microarray.

In view of the foregoing, Applicant respectfully submits that the rejections of claims 2 and 33 under 35 U.S.C. §102(b) are untenable and request their withdrawal.

CONCLUSION

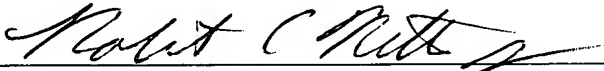
It is respectfully requested that the amendments presented herewith be entered in this application, since the

amendments are primarily formal, rather than substantive in nature. This amendment is believed to clearly place the pending claims in condition for allowance. In any event, the claims as presently amended are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

In view of the amendments presented herewith and the foregoing remarks, it is respectfully urged that the rejections set forth in the November 9, 2006 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned at the phone number given below.

Respectfully submitted,
DANN, DORFMAN, HERRELL AND SKILLMAN
A Professional Corporation

By 
Robert C. Netter, Jr., Ph.D.
PTO Registration No. 56,422

Telephone: (215) 563-4100
Facsimile: (215) 563-4044